

AMENDED IN SENATE APRIL 26, 2006

AMENDED IN SENATE APRIL 6, 2006

SENATE BILL

No. 1260

Introduced by Senators Ortiz and Runner

February 9, 2006

An act to amend Sections 125118, ~~125118.5~~, 125119, 125119.3, and 125119.5 of, and to add Chapter 2 (commencing with Section 125330) to Part 5.5 of Division 106 of, the Health and Safety Code, relating to reproductive health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1260, as amended, Ortiz. Reproductive health and research.

The California Stem Cell Research and Cures Act, an initiative measure approved by the voters at the November 7, 2004, general election (Proposition 71), establishes the California Institute for Regenerative Medicine, the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in, the cure for, or substantial mitigation of, diseases and injuries. Existing law establishes the Independent Citizen's Oversight Committee (ICOC), composed of appointed members, that is required to perform various functions and duties with regard to the operation of the institute, including, but not limited to, establishing standards applicable to research funded by the institute.

Existing law prohibits amendment of Proposition 71 by the Legislature unless the amendment is approved by the voters, or the amendment is accomplished by a bill introduced after the first 2 full calendar years and approved by a vote of 70% of both houses.

Existing law, which is not applicable to research funded under Proposition 71, and which would be repealed on January 1, 2007, requires the State Department of Health Services to, among other things, develop guidelines for research involving the derivation or use of embryonic stem cells, ~~to establish an advisory committee~~, and to report annually to the Legislature.

This bill would delete the repeal date of those provisions, thus indefinitely extending their duration.

Existing law applicable to fertility treatment requires that a physician and surgeon provide a patient with prescribed information and obtain the patient's informed consent prior to providing the fertility treatment.

This bill, with certain exceptions, would require a physician and surgeon, prior to ~~providing~~ *conducting* assisted oocyte production, as defined, or other method of ovarian retrieval for purposes of retrieving eggs for research or for developing medical therapies, to provide the subject with a standardized written summary of health and consumer issues and to obtain the subject's written and oral informed consent for the procedure.

Existing law prohibits a person from knowingly, for valuable consideration, purchasing or selling embryonic or cadaveric fetal tissue for research purposes.

This bill would prohibit human oocytes or embryos from being acquired, sold, offered for sale, received, or otherwise transferred for valuable consideration for medical research or development of medical therapies, and would prohibit payment in excess of the amount of reimbursement of expenses to be made to any research subject to encourage her to produce human oocytes for the purposes of medical research.

The bill would declare that it is not to be construed to amend Proposition 71, and would encourage the ICOC to take prescribed actions, including, but not limited to, reviewing studies concerning the health risks and benefits of ovarian stimulation drugs, and undertaking further research.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 ~~(a) There is significant need for research, analysis,~~
4 ~~understanding of health effects, and formulation of standardized~~
5 ~~policies and procedures in the areas of subject protection and~~
6 ~~education for research involving ovarian stimulation, oocyte~~
7 ~~retrieval, and any alternative method of oocyte retrieval.~~

8 *(a) The purpose of this act is to create protections for research*
9 *subjects and it should not be construed to affect any other form*
10 *of medical care.*

11 (b) Scientific research can be most effectively achieved by
12 establishing protocols to protect, respect, and promote human
13 health, safety, dignity, autonomy, and rights in conducting
14 research.

15 (c) This act seeks to support the requirements already in
16 current law upholding the principle of voluntary and informed
17 consent and to tailor them to this new area of pioneering research
18 that utilizes human oocytes.

19 (d) The potential for exploitation of the reproductive
20 capabilities of women for commercial gain raises health and
21 ethical concerns that justify the prohibition of payment for
22 human oocytes.

23 SEC. 2. Section 125118 of the Health and Safety Code is
24 amended to read:

25 125118. (a) ~~On or before January 1, 2005, the~~ *The*
26 department shall develop guidelines for research involving the
27 derivation or use of human embryonic stem cells in California.

28 (b) In developing the guidelines specified in subdivision (a),
29 the department may consider other applicable guidelines
30 developed or in use in the United States and in other countries,
31 including, but not limited to, the Guidelines for Research Using
32 Human Pluripotent Stem Cells developed by the National
33 Institutes of Health and published in August 2000, and corrected
34 in November 2000 , *and the Guidelines for Human Embryonic*
35 *Stem Cell Research issued by the National Research Council and*
36 *Institute of Medicine of the National Academies in 2005.*

1 ~~(e) The department may contract with a public or private~~
2 ~~organization, to the extent permitted by state law, for assistance~~
3 ~~in developing the guidelines.~~

4 ~~SEC. 3. Section 125118.5 of the Health and Safety Code is~~
5 ~~amended to read:~~

6 ~~125118.5. (a) For purposes of developing the guidelines~~
7 ~~required by Section 125118, the director shall establish a Human~~
8 ~~Stem Cell Research Advisory Committee.~~

9 ~~(b) The advisory committee shall consist of 13 members, as~~
10 ~~follows:~~

11 ~~(1) Seven scientists with experience in biomedical research in~~
12 ~~the fields of cell differentiation, nuclear reprogramming, tissue~~
13 ~~formation and regeneration, stem cell biology, developmental~~
14 ~~biology, regenerative medicine, or related fields.~~

15 ~~(2) Two medical ethicists.~~

16 ~~(3) Two persons with backgrounds in legal issues related to~~
17 ~~human embryonic stem cell research, in vitro fertilization, or~~
18 ~~family law, as it applies to the donation of embryos and oocytes.~~

19 ~~(4) Two persons who are members or leaders of religious~~
20 ~~organizations.~~

21 ~~SEC. 4.~~

22 ~~SEC. 3. Section 125119 of the Health and Safety Code is~~
23 ~~amended to read:~~

24 ~~125119. (a) (1) All research projects involving the~~
25 ~~derivation or use of human embryonic stem cells shall be~~
26 ~~reviewed and approved by an institutional review board that is~~
27 ~~established in accordance with federal regulations, including Part~~
28 ~~46 (commencing with Section 46.101) of Subchapter A of~~
29 ~~Subtitle A of Title 45 of the Code of Federal Regulations, prior to~~
30 ~~being undertaken. Any such institutional review board shall, in~~
31 ~~its review of human embryonic stem cell research projects,~~
32 ~~consider and apply the guidelines developed by the department~~
33 ~~pursuant to Section 125118. An institutional review board may~~
34 ~~require modifications to the plan or design of a proposed human~~
35 ~~embryonic stem cell research project as a condition of approving~~
36 ~~the research project.~~

37 ~~(2) For purposes of this article, "IRB" means an institutional~~
38 ~~review board described in paragraph (1).~~

39 ~~(b) Not less than once per year, an IRB shall conduct~~
40 ~~continuing review of human embryonic stem cell research~~

1 projects reviewed and approved under this section in order to
2 ensure that the research continues to meet the standards for IRB
3 approval. Pursuant to its review in accordance with this
4 subdivision, an IRB may revoke its prior approval of research
5 under this section and require modifications to the plan or design
6 of a continuing research project before permitting the research to
7 continue.

8 ~~SEC. 5.~~

9 *SEC. 4.* Section 125119.3 of the Health and Safety Code is
10 amended to read:

11 125119.3. (a) Each IRB that has reviewed human embryonic
12 stem cell research pursuant to Section 125119 shall report to the
13 department, annually, on the number of human embryonic stem
14 cell research projects that the IRB has reviewed, and the status
15 and disposition of each of those projects.

16 (b) Each IRB shall also report to the department regarding
17 unanticipated problems, unforeseen issues, or serious continuing
18 investigator noncompliance with the requirements or
19 determinations of the IRB with respect to the review of human
20 embryonic stem cell research projects, and the actions taken by
21 the IRB to respond to these situations.

22 ~~SEC. 6.~~

23 *SEC. 5.* Section 125119.5 of the Health and Safety Code is
24 amended to read:

25 125119.5. (a) The department shall at least annually review
26 reports from IRBs pursuant to Section 125120, and may revise
27 the guidelines developed pursuant to Section 125118, as it deems
28 necessary.

29 (b) The department shall report annually to the Legislature on
30 human embryonic stem cell research activity. These annual
31 reports shall be compiled from the reports from IRBs pursuant to
32 Section 125120.

33 ~~SEC. 7.~~

34 *SEC. 6.* Chapter 2 (commencing with Section 125330) is
35 added to Part 5.5 of Division 106 of the Health and Safety Code,
36 to read:

37
38 CHAPTER 2. PROCURING OF OOCYTES FOR RESEARCH

39
40 125330. The following definitions shall apply to this chapter:

(a) “Assisted oocyte production” or “AOP” means *surgical extraction of oocytes following* pharmaceutically induced manipulation of oocyte production through the use of ovarian stimulation.

(b) “Oocyte” means a female egg or egg cell of a human female.

(c) “Subject” means any person undergoing AOP or any alternative method of ovarian retrieval for research or for the development of medical therapies, including those who would not meet the definition of “subject” under 45 C.F.R. 46.102.

(d) “*Alternate method of oocyte retrieval*” means a method of oocyte retrieval that does not involve the pharmaceutically induced manipulation of oocyte production.

125335. (a) Prior to ~~providing~~ *conducting* AOP or any alternative method of ovarian retrieval ~~to~~ on a subject for the purpose of procuring oocytes for research or the development of medical therapies, a physician and surgeon shall provide to the subject a standardized medically accurate written summary of health and consumer issues associated with AOP and any alternative methods of oocyte retrieval. The failure to provide to a subject this standardized medically accurate written summary constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

(b) The summary shall include, but not be limited to, medically accurate disclosures concerning the potential risks of AOP ~~and~~ *or* any alternative method of oocyte retrieval, including the risks associated with *the surgical procedure and with* using the drugs, medications, and hormones prescribed for ovarian stimulation during the AOP process or any alternative method of oocyte retrieval.

(c) For purposes of subdivision (a), “written summary of health and consumer issues” means the guide published and updated by the American Society for Reproductive Medicine entitled, “Assisted Reproductive Technology: A Guide for Patients” or an alternative written medically accurate document prepared by a recognized authority on oocyte retrieval for medical research that also meets the criteria included in this section. This alternative document may be one that has been approved and recommended by the State Department of Health

1 Services pursuant to Section 125118 and shall include all of the
2 following:

3 (1) The document shall adhere to simplified reading standards,
4 including, but not limited to, those generally accepted and
5 required for government publications. The document shall be
6 written in ~~layman's~~ *layperson's* language and shall be made
7 available in languages spoken by subjects in the study if their
8 proficiency is largely in a language other than English. All
9 information in the document shall be conveyed to the subject
10 orally in easy to understand and nontechnical terms.

11 ~~(2) The document shall include information on the state of the~~
12 ~~science in the area of assisted reproductive technology.~~

13 ~~(3)~~

14 (2) The document shall include additional resources for, or list
15 additional sources of, medical information on health and safety
16 issues surrounding oocyte retrieval. ~~This information may~~
17 ~~include, but is not limited to, brochures, information on Internet~~
18 ~~Web sites, telephone numbers for oral medical advice, and~~
19 ~~publications, and shall be produced by recognized scientific,~~
20 ~~research, academic entities, governmental entities, and credible~~
21 ~~private institutions.~~

22 125340. (a) Prior to providing AOP or any alternative
23 method of ovarian retrieval to a subject for the purposes of
24 medical research or development of medical therapies, a
25 physician and surgeon shall obtain written and oral informed
26 consent for the procedure from the subject. ~~The written informed~~
27 ~~consent document shall include all of the following:~~ *Informed*
28 *consent for the purposes of this chapter shall comply with the*
29 *informed consent requirements of the Protection of Human*
30 *Subjects in Medical Experimentation Act (Chapter 1.3*
31 *(commencing with Section 24170) of Division 20).*

32 ~~(1) A statement that the subject has received and reviewed the~~
33 ~~summary of health and consumer issues required in Section~~
34 ~~125335.~~

35 ~~(2) A statement informing the subject that oocytes may not be~~
36 ~~sold or transferred for valuable consideration except as set forth~~
37 ~~in Section 125350.~~

38 ~~(3) A summary of the arrangements the procuring entity has~~
39 ~~made for coverage or payment for medical care related to AOP or~~
40 ~~any alternative method of oocyte retrieval.~~

~~(4) Disclosure as to whether the physician or surgeon and his or her immediate family members have any professional interest in the outcome of the research or of the oocyte retrieval procedure.~~

~~(5) If the physician conducting the oocyte retrieval is also an investigator in the research, disclosure that he or she carries the interest of both the subject and the success of the research, and that the subject has a right to a second opinion if she has any medical concerns.~~

~~(6) Disclosure of alternative methods of oocyte retrieval.~~

~~(7) A statement that there is no expected benefit to the subject from the research.~~

~~(8) A statement that the consent to participate in the procedures may be withdrawn at any time and the subject may discontinue participation in the procedure without prejudice.~~

~~(9) A statement that the subject has the opportunity to consent or to withhold consent to the procedures without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.~~

(b) The failure to obtain written informed consent from the subject constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code. Nothing in this section shall be construed to relieve the physician and surgeon from other existing duties under the law, including, but not limited to, the duty to obtain a subject's informed consent after fully explaining the proposed procedure. The requirement that a physician and surgeon provide the standardized written summary pursuant to Section 125335 is in addition to, and does not supplant, other existing legal requirements regarding informed consent, including, but not limited to, compliance with the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20.

(c) This section shall not affect the suitability or availability of oocytes procured for research before January 1, 2006, if the oocytes were donated pursuant to protocols or standards that are generally recognized and accepted by national or international scientific bodies.

(d) Any written document required pursuant to this section shall adhere to simplified reading standards, including, but not

limited to, those generally accepted and required for government publications, and in ~~layman's~~ *layperson's* language. The document shall be made available in languages spoken by subjects in the study if their proficiency is largely in a language other than English. All information in the written informed consent document shall also be conveyed to the subject orally in easy to understand and nontechnical terms.

125341. An institutional review board (IRB) that reviews and approves medical and scientific research shall require all of the following of any research program or project that comes under its review that involves AOP or any alternative method of oocyte retrieval:

(a) That it include a written summary as required under Section 125335 that would include information on health risks and potential adverse consequences of the procedure and describe the manner in which the subject will receive and review this written summary.

(b) That it obtain informed consent in compliance with the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20).

(c) That it provide the subject with an objective and accurate statement about the existing state of the research for which the subject is providing oocytes.

~~(a)~~
(d) That it perform psychological and physical screening for all subjects prior to the oocyte retrieval procedure, following generally recognized standards for the subject's health and safety.

~~(b)~~
(e) That it ensure that after ~~providing~~ conducting AOP or any alternative method of oocyte retrieval to on a subject, the subject be given a postprocedure medical examination at a time within the standard of care to determine if the subject has experienced an adverse health effect that is a ~~consequence~~ result of the procedure. The subject shall be informed that she has the right to a second opinion if she has any medical concerns.

~~(c)~~
(f) That it ensure that ~~after the postprocedure examination in subdivision (b)~~, the subject has access to and coverage for medical care for any adverse consequence that is a direct and

1 proximate result of the procedure. The research program or
2 project shall ensure that payment~~for~~ or coverage of resulting
3 medical expenses be provided by the program or project *and that*
4 *a summary of the arrangements the procuring entity has made*
5 *for coverage or payment for medical care related to AOP or any*
6 *alternative method of oocyte retrieval is provided to the subject*
7 *prior to the procedure.*

8 (g) *That it provide a summary informing the subject that*
9 *oocytes may not be sold or transferred for valuable consideration*
10 *except as set forth in Section 125350.*

11 (h) *That it provide disclosure if the physician and surgeon and*
12 *his or her immediate family members have any professional*
13 *interest in the outcome of the research or of the oocyte retrieval*
14 *procedure and, if so, that it provide disclosure that he or she*
15 *carries the interest of both the subject and the success of the*
16 *research.*

17 ~~(d)~~

18 (i) That it establish and maintain a written record to include,
19 but not be limited to, all of the following components, which
20 information shall be made publicly available, ~~shall not disclose~~
21 ~~individual information about subjects, and shall be confidential~~
22 ~~and is deemed protected by subject privacy provisions in current~~
23 ~~law; on at least a biennial basis:~~

24 (1) The demographics of subjects, including, but not limited
25 to, their age, race, primary language, ethnicity, income bracket,
26 and ZIP Code of current residence.

27 (2) Information for every oocyte, sperm, gamete, somatic cell,
28 embryo donation, or product of somatic cell nuclear transfer that
29 has been donated, created, or used. This record should be
30 sufficient to determine the provenance and disposition of those
31 materials.

32 (3) A record of all adverse health outcomes ~~of, including, but~~
33 ~~not limited to, incidences and degrees of severity, resulting from~~
34 ~~the AOP or any alternative method of oocyte retrieval, including,~~
35 ~~but not limited to, incidences and degrees of severity of Ovarian~~
36 ~~Hyperstimulation Syndrome.~~

37 ~~(e) Include an informed consent document and a written~~
38 ~~summary that would include information on health risks and~~
39 ~~potential adverse consequences of the procedure as required~~
40 ~~under Sections 125335 and 125340. The subject shall be given an~~

1 ~~objective and accurate statement about the existing state of the~~
2 ~~research for which the subject is providing oocytes.~~

3 (j) *The information included in the written record pursuant to*
4 *subdivision (i) shall not disclose individual information about*
5 *subjects, and shall be confidential and is deemed protected by*
6 *subject privacy provisions of law.*

7 125343. Any employee or relative of an employee of a
8 research organization or body is prohibited from being a subject
9 in the research.

10 125344. The physician and surgeon performing the AOP or
11 any alternative method of oocyte retrieval shall not have a
12 financial interest in the outcome of the research.

13 125345. Pursuant to guidelines adopted by the *Research*
14 *Council and Institute of Medicine of the National Academies of*
15 *Sciences*, researchers shall offer subjects an opportunity to
16 document their preferences regarding future uses of their donated
17 materials. *The consent process shall fully explore whether donors*
18 *have objections to any specific forms of research to ensure that*
19 *their wishes are honored.*

20 125346. Any procedures for procuring oocytes in this state
21 for research or the development of medical therapies shall meet
22 all of the standards for subjects included in this chapter. All eggs
23 procured outside of this state for research taking place in this
24 state shall meet these same standards. *All egg extractions for*
25 *research shall be approved by an institutional review board*
26 *pursuant to Section 125341.*

27 125350. No human oocyte or embryo shall be acquired, sold,
28 offered for sale, received, or otherwise transferred for valuable
29 consideration for the purposes of medical research or
30 development of medical therapies. For purposes of this section,
31 “valuable consideration” does not include reasonable payment
32 for the removal, processing, disposal, preservation, quality
33 control, and storage of oocytes or embryos.

34 125355. No payment in excess of the amount of
35 reimbursement of direct, out-of-pocket expenses shall be made to
36 any research subject to encourage her to produce human oocytes
37 for the purposes of medical research. There shall be no
38 reimbursement for lost wages.

1 ~~SEC. 8.~~

2 *SEC. 7.* (a) This act shall not be construed to amend
3 Proposition 71, approved by the voters at the November 2, 2004,
4 general election.

5 (b) The Independent Citizen's Oversight Committee (ICOC)
6 established pursuant to Section 125290.15 of the Health and
7 Safety Code is encouraged to review existing studies concerning
8 the health risks and benefits of ovarian stimulation drugs used for
9 assisted oocyte production, identify gaps in existing knowledge
10 concerning health risks and benefits, and ~~to~~ undertake further
11 research as the ICOC deems necessary to characterize the risks
12 and benefits of those drugs.